

Rec'd
8 Oct-09

James R. Overman
Precision Herbs L.L.C.
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330-276-6511

October 5th, 2009

U. S. Food and Drug Administration
Karen Gale Sego
Compliance Officer
6751 Steger Dr.
Cincinnati, OH. 45237-3097

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

Re: Notice of Non-Compliance with the Privacy Act Involving said Respondent.

Dear Ms. Sego:

This letter is our official notice to your agency that it has not complied with the Federal Privacy Act of 1974 (Title 5 U.S.C. § 552a). The Privacy Act requires your agency to answer five (5) questions automatically before any inspection for information or data is provided to your agency. Unless your agency is exempt from the Privacy Act, your examination, inspections, investigations and inquiries, etc. of our entities is premature, illegal, bogus, erroneous and represents a fatal defect of the required legal procedures involving your agency. In other words, the information and excessive data you have obtained to date from your inspections are tainted and cannot be used against us in any matter. Your agency is in violation of the 4th and 5th Amendments of the U.S. Constitution from the start of your investigation. Again, the Privacy Act of 1974, Freedom of Information Act of 1966 and numerous court decisions (i.e., U.S. v. Powell 327 U.S. 217, Pacific Mills v. Kenefick 99 F. 2d 188, Oklahoma Press Publishing Co. v. Walling 327 U.S. 217, Sherar v. Cullen 481 F. 2d 945 and others require that the FDA first inform the respondent in writing of certain information when requested. Our requests are as follows to be answered separately. The next five (5) items are from the Privacy Act of 1974. (Items 1 thru 5).

1. Please state the authority (specific section of the FDA Code or statute) for the solicitation of the information you desire.

2. Please state whether disclosure of such information is mandatory or voluntary. If mandatory, what penalties will result for non-compliance?
3. Please state the principal and specific purpose or purposes for which the information is to be used in any capacity.
4. Please state the routine uses which may be made of the information or any other use of the information.
5. Please state the effects on the respondent if not provided the information requested.
6. Please explain and show that the investigation is of the kind authorized by Federal Statute.
7. Please explain why and how the demand for information is not too vague and broad in scope.
8. Please explain and show that information sought is relevant or material to a lawful subject of inquiry.
9. Please explain how and why the investigation is pursuant to a legitimate purpose.
10. Please explain how and why the inquiry for information may be relevant to the purpose.
11. Please show and prove that the information is not already in your possession or cannot be obtained from other sources.
12. Please show and prove that the Secretary or his delegate of the FDA has determined that the further examination is necessary.
13. Please show and prove that the other administrative steps required by the FDA Code or Statute have been followed to the letter of the law.

The decisions and order(s) made under the fraudulent agency investigation cannot stand.

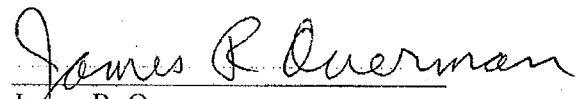
One cannot break the law in an attempt to "uphold the law".

An agency of the government must scrupulously observe rules, regulations or procedures which it has established. When it fails to do so, its action cannot stand and courts will strike it down. United States ex rel. Accardi v. Shaughnessy, 347 U.S. 260, 74 S.Ct. 499, 98 L.Ed. 681; United States v. Heffner, 420 F.2d 809; Service v. Dulles, 1 L.Ed. 2d 1403; Nelson v. I.N.S., 232 F. 3d 258.

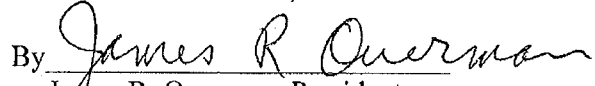
A remedy for the grave injustice done to Respondent by the FDA agency in this instant case would be to strike down any orders against the respondent or have a higher court do so, and thereby set a legal precedent in a reported court decision. We are prepared to proceed with a public court forum, if necessary.

In addition, we request that any and all information, documents, notes, etc. from the investigation be immediately returned to us since they were obtained illegally and erroneously in violation of the law.

Sincerely,


James R. Overman

Precision Herbs L.L.C.,

By 
James R. Overman, President